LATTA.002C3





**PATENT** 

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicant** 

Latta, Paul P.

Appl. No.

10/660,924

Filed

September 12, 2003

For

PREVENTION OF DIABETES

THROUGH INDUCTION OF

**IMMUNOLOGICAL** 

**TOLERANCE** 

Examiner

Belyavski, Michail A.

Group Art Unit

1644

### SECOND DECLARATION OF DAVID SCHARP, M.D. UNDER 37 C.F.R §1.132

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### Dear Sir:

- 1. I, David Scharp, M.D., am Chief Scientific Officer of Novocell, Inc. At Novocell I am actively engaged in research related to development of treatment of diabetes using encapsulated insulin-producing cells.
- 2. I have extensive experience in the field of the claimed invention as indicated in the attached Curriculum Vitae provided herewith as Exhibit A.
- 3. There are two potential animal models for studying Type I diabetes, the BB rat and the NOD mouse. The BB rat, while developing diabetes, has a multitude of immunologic disorders that makes it more of a model for immune deficiency than diabetes. The BB rat is no longer considered an acceptable model for studying human autoimmune diabetes.
- 4. The NOD mouse is therefore, the only animal model for human autoimmune, Type I diabetes in that it is predictive of human disease. Its lymphocytes spontaneously begin attacking

10/660,924

Filed

September 12, 2003

its insulin-producing pancreatic beta cells soon after birth. Looking at the histology of the pancreas of these mice during the autoimmune process, one finds early that most islets are infiltrated with immune cells that are destroying islets. As the process continues towards the diabetic phase, almost all of the beta cells are destroyed leaving smaller than normal islets with residual inflammation that continues to destroy the new islets that are stimulated to develop due to the failing islet mass. This ongoing destruction of the insulin-producing pancreatic beta cells continues and progresses for 15 to 32 weeks until a sufficient number of beta cells are destroyed to cause the clinical onset of Type I diabetes in NOD mice. Examining living NOD mice prior to development of clinical diabetes, including monitoring their blood glucose levels, one would have no clue that this autoimmune process is actively destroying their pancreatic beta cells. Yet, if one examines their blood for anti-islet protein antibodies, one can clearly identify those animals that will eventually lose blood glucose control and develop clinical diabetes. This situation is identical for human Type I diabetes in that patients at high risk for developing Type I diabetes are tested for the presence of specific auto-antibodies. The number and titers of these specific antibodics can now predict with >90% certainty which of these patients with ongoing autoimmune destruction of their beta cells will actually develop clinical Type I diabetes within 5 years.

- 5. By following a large number of patients over time, it has been determined that there are clearly many years available in which to intervene in the auto-immune process prior to the development of clinical diabetes in an attempt to prevent it, if there were an effective prevention method available. Six drugs have been tried in patients with documented evidence of autoimmune diabetes to determine if human diabetes can be prevented. To date, such drug treatments have not been effective in preventing clinical diabetes in humans.
- 6. Our approach is totally different in that we are not giving drugs to prevent diabetes. Instead, we are implanting a very small fraction of encapsulated islet allografts into these NOD mice prior to the development of clinical diabetes in order to stop the onset of clinical, Type I diabetes. This fraction of encapsulated islets is so small it would have no effect on controlling blood glucose if given after diabetes had begun and therefore, is not a treatment for diabetes. We believe that the continuous release of donor antigens from the small fraction of encapsulated

Appl. No. : 10/660,924

Filed: September 12, 2003

islets that are not destroyed by the host, alters the auto-immune response in a way that the host no longer considers the islets to be foreign. In this way, the immune attack on the islets within the pancreas stops prior to the onset of clinical diabetes and thus prevents clinical diabetes.

- 7. In my previous declaration, filed on April 1, 2004, I presented the data from the NOD mouse study on Prevention of Type I diabetes. This data has now been summarized into two bar graphs to allow an easier analysis.
- 8. Islets from mouse strain C57B1/6 were encapsulated by polyethylene glycol conformal coating as described in USP 5,529,914. This patent was incorporated by reference into the specification of the application captioned above. The conformally-coated islets were implanted by intraperitoneal injection into NOD mice. The experiment had two variables under study time of implantation of the encapsulated islets (4, 8, and 12 weeks) and number of islets implanted (50, 100 and 150 islet equivalents, IEQ).
- 9. Exhibit 1 shows the data for all animals grouped by time of implantation. Implantation at 4 weeks showed the best results with diabetes being prevented in 60% of the treated animals, as compared to the control animals with none having diabetes prevented.
- 10. Exhibit 2 shows the data for all animals grouped by number of islets implanted. A dose of 50 IEQ produced the best results with diabetes being prevented in 60% of the treated animals. All the control animals developed diabetes.
- 11. Exhibit 3 demonstrates that in the control recipients (NOD mice not implanted with encapsulated islet cells), the autoimmune destruction of the pancreatic islets is very complete with small shrunken islets remaining with continuing evidence of lymphocytes destroying any new islets that are formed.
- 12. Exhibits 4 & 5 demonstrate that in those recipients that were prevented from developing diabetes after implanting the small quantity of encapsulated islets, very large islets (many times their normal size) are present, without evidence of host lymphocyte destruction. This means that the normal process in the mouse to replace lost islets has been successful to the point of preventing diabetes from destroying all of the newly formed islet cells.
- 13. This demonstrates that the method of the present invention prevents type I diabetes.

10/660,924

Filed

: September 12, 2003

14. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or patent issuing therefrom.

Dated:

Rv

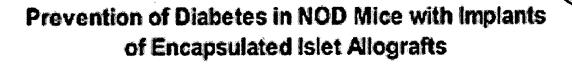
David Scharp

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10/660,924

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**September 12, 2003** 



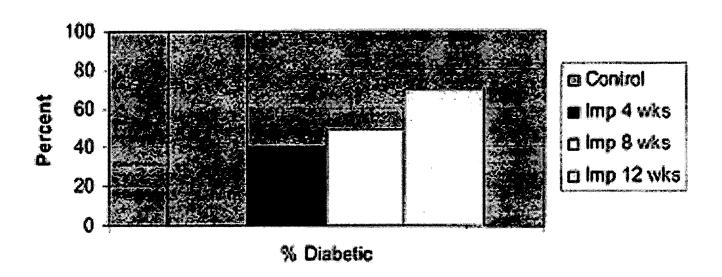


Exhibit 1

10/660,924

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September 12, 2003

## Prevention of Diabetes in NOD Mice with Implants of Encapsulated Islet Allografts

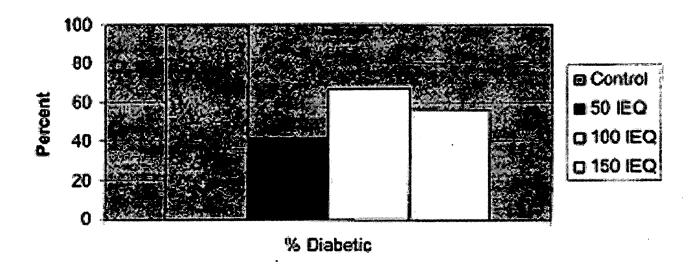


Exhibit 2

Appl. No. Filed

10/660,924 September 12, 2003

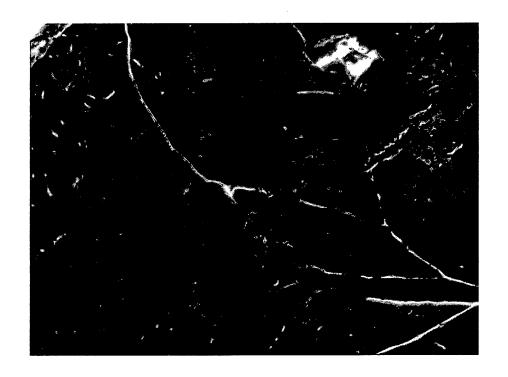


Exhibit 3

Appl. No. Filed

10/660,924 September 12, 2003

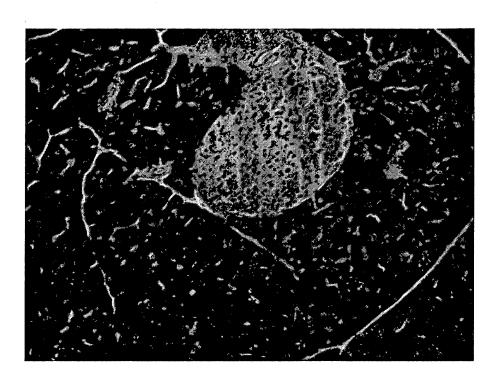


Exhibit 4



Exhibit 5

# Exhibit A

#### **CURRICULUM VITAE**

#### David William Scharp, M.D.

Born: July 5, 1945

Washington, Illinois

Social Security Number: 327-36-7524

Marital Status: Wife: Jeanette

Children: Kevin Scharp

Daniel Scharp Anna Scharp David Bondurant Melissa Bondurant

Pre-Medical Education: University of Missouri

Columbia, Missouri

1963-1966

Medical Education: Washington University School of Medicine

St. Louis, Missouri

1966-1970

#### **Graduate Hospital Experience:**

Intern in Surgery 7/1/70-6/30/71
Barnes Hospital/Washington University

Surgical Resident 7/1/71-6/30/72 & 7/1/74-6/30/76 Barnes Hospital/Washington University

Surgical Research Fellow 7/1/72-6/30/74 Washington University - Department of Surgery

#### **Academic Positions:**

Assistant Professor of Surgery 1976-1983 Washington University School of Medicine

Associate Professor of Surgery 1983-1991 Washington University School of Medicine

Professor of Surgery 1991-President Washington University School of Medicine

Leave of Absence 1/1/94-7/1/95

#### **Commercial Positions:**

Novocell, Inc. Chief Scientific Officer

Neocrin Company
Chief Scientific Officer 1/1/94-7/31/99
Executive Vice President of Medical Affairs 1/1/94-7/31/99
Executive Vice President for Research 1/1/94-11/1/95
Executive Vice President, Research and Development 11/1/95-President

McDonnell Douglas Corporation 1984-1987 Contractual Research Investigator Electrophoretic Separation of Islet Cells

Cytotherapeutics, Inc. 1989-1993 Founding Scientist Scientific Advisory Board Member Contractual Research Investigator

#### Patents:

```
"Islet Isolation Process"
DE191613T - 1987
DE3650662D - 1998
EP0191613 - 1986
EP0191613 - 1989
EP0191613 - 1997
JP61183226 - 1986
US4868121 - 1989
US5322790 - 1994
"Method to Isolate Clusters of Cell Sub-Types from Organs"
AU1934988 – 1989
CA1340406 – 1999
EP0382727 - 1990
EP0382727 - 1991
JP2504222T - 1990
US5079160 - 1992
WO8809667 - 1988
"Implantable Biocompatible Immunoisolatory Vehicle for Delivery of Selected Therapeutic
Products"
AT156344T - 1997
AU666118 – 1996
AU682796 – 1997
AU2004192 - 1992
AU3902095 - 1996
CA2109085 - 1992
CA2109085 - 2003
DE69221484D - 1997
DE69221484T - 1998
DK585368T - 1998
EP0585368 - 1994
EP0585368 - 1994
EP0585368 – 1997
ES2107537T - 1997
FI934545 – 1993
FI934545D - 1993
GR3025301T - 1998
HK1001832 - 1998
JP6507412T - 1994
NO308198B - 2000
NO933842 - 1993
SG47470 - 1998
```

US5798113 - 1998

US5800828 - 1998

US5871767 – 1999

US6083523 - 2000

US6322804 - 2001

US2002150603 - 2002

WO9219195 - 1992

"Methods for Coextruding Immunoisolatory Implantable Vehicles with a Biocompatible Jacket and a Biocompatible Matrix Core"

US5800829 - 1998

"Methods for Treating Diabetes by Delivering Insulin from Biocompatible Cell Containing Devices"

US5869077 - 1999

"Methods for Making Immunoisolatory Implantable Vehicles with a Biocompatible Jacket and a Biocompatible Matrix Core"

US5834001 - 1998

US5874099 -1999

"Use of Pouch for Implantation of Living Cells"

AU4788993 - 1994

CA2140905 - 1994

EP0655910 - 1995

EP0655910 - 1996

JP8500033T - 1996

US5916554 - 1999

WO9403154 -- 1994

#### **Hospital Appointments:**

Assistant Surgeon 1976-1983

Associate Surgeon - 1983-Present

Barnes Hospital, St. Louis, Missouri

Attending Surgeon 1982-1985

Consulting Surgeon 1976-1982

Associate Chief of Surgery 12/86-9/90

Veterans Administration Medical Center, St. Louis, Missouri

Consulting Surgeon 1985-7/95 Acting Chief of Surgery 3/86-12/86 St. Louis Regional Hospital, St. Louis, Missouri

Consulting Surgeon 1976-1985 St. Louis Children's Hospital, St. Louis, Missouri

Consulting Surgeon 1976-1985 Chief of Surgery 1981-1982 St. Louis County Hospital, St. Louis, Missouri

Attending Surgeon 1976-1982 St. Louis City Hospital, St. Louis, Missouri

Licensure: Missouri 1970

Certification: American Board of Surgery 1979

Fellow American College of Surgery 1982

Recertification: American Board of Surgery 1989

#### Medical Societies:

American College of Surgeons
American Diabetes Association
American Federation of Clinical Research
American Pancreatic Association
American Society for Artificial Internal Organs
American Surgical Association
Association for Academic Surgery
Society of University Surgeons
Tissue Culture Association
American Society of Transplant Surgeons
The Cell Transplantation Society
United Network of Organ Sharing - Region 8
International Pancreas & Islet Transplantation Association

#### **Honors and Awards:**

St. Louis Surgical Society Award for Research Recipient 1973 & 1974
NIH Research Career Development Award Recipient 1977-1982
NIH NAIMMDD Site Visit Teams Member 1980-1995 NIH Surgery, Anesthesiology, and Trauma Study Section

Member 1985-1989

Reserve Member Status 1989-1995

World Journal of Surgery

Guest Editor - Islet Transplantation Symposium 1984

"Separation of Islet Cells in Microgravity by Continuous-Flow Electrophoresis", NASA - McDonnell Douglas Astronautics Corp. - STS-8, Space Shuttle, "Challenger", Experiment 1984

#### Editorial Reviewer:

Diabetes, Surgery, Journal Clinical Investigation

Grant Reviewer

Canadian Diabetes Association

Medical Research Council of Canada

National Surgical Advisor - Digestive Disease Center of Excellence -

The Humana Corporation 1986-1994

Alpha Omega Alpha - Washington University Chapter - Elected

Faculty Member January 1988

Outstanding Profession/Scientific Employee - Federal Employee of the Year Award Program - St. Louis Federal Executive Board 1990

The Huddinge Hospital Transplant Lectureship - Annual Meeting of the Swedish Society for Medical Science, Stockholm, Sweden, December 1990

Council Member - Cell Transplantation Society 1992-Present

Council Member - International Pancreas & Islet Transplantation Association 1993-Present Editorial Board

Cell Transplantation 1992-1993

Transplantation Science

#### Committee Appointments:

Washington University Animal Studies Committee

Chairman 1991-1994

Washington University Medical Center Alumni Association

Committee Member 1991-1994

International Juvenile Diabetes Research Foundation Medical Science Review Committee 1990-1993

UNOS Pancreas Subcommittee Member 1991-1995

American Society of Transplant Surgeons Program and Publications Committee 1989-1991

Academic Freedom and Tenure Hearing Committee

Member 1985-1991

Washington University Committee on the Humane Care of Laboratory Animal Member Member 1984-1990

Operating Room Technician Program

Forest Park Community College

Advisory Committee 1976-1995

Chairman 1986-1995

Mid-America Transplant Association

Member Professional Advisory Board 1985-1995

American Cancer Society Institutional Research Grants

Washington University Committee for Cancer Research

Member 1979-1989

Chairman 1982-1989

"Health Views" - Editorial Advisory Board

Member 1984-1988

American Diabetes Association, St. Louis Chapter

Research Committee 1985-1988

Department of Surgery Animal Facility

Director 1980-1984

Washington University Faculty Senate

Member 1981-1983

**Executive Committee of the Faculty Council** 

Member 1982-1984

Clinical Sciences Research Building Animal Surgery Suite

Director 1984-1985

Department of Engineering Master Degree Thesis Review Committee:

1979-John Bergen - "Kinetics of Insulin Secretion from Pancreatic Islets of Langerhans and Development of Islet Transplantation Chambers"

1980-Paul Aegerter - "Microencapsulation of Living Cells to Prevent Immunological Response"

1983-Shiow Meei Lin - "Testing of a Mathematical Model for Islet Transplantation Chambers"

1987-Donna Wilkinson - "Coating of Live Cells with Polysaccharide Derivatives"

1989-Mary Blanchard - "Quantification of Low Concentrations of Polysaccharide Derivatives and Their Effect on Cell Viability"

1990-Ph.D. Thesis Review, Donna Hawk-Reinhard - "Purification of Pancreatic Islets of Langerhans Using Cell Electrophoresis"

St. Louis VAMC Committees

Comprehensive Planning Committee

Chairman 1988-1990

Administrative Executive Board 1988-1990

Professional Standards Board 1988-1990

Research Committee 1988-1994

District Planning Board 1988-1990

#### **Barnes Hospital Committees**

Chaplaincy Committee 1992-1994

**Emergency Room Committee 1978-1984** 

Search Committee for ER Director 1978-1984

Patient Education Parent Committee 1979

Surgery Patient Education Subcommittee Chairman 1981-1988

Tissue Culture Association

Publicity Chairman 1980

#### **Invited Presentations, Selected:**

#### The Kroc Foundation

Islet Transplantation Workshop 1974

Islet Transplantation Workshop 1979

Islet Transplantation Workshop 1982

#### National Institutes of Health

National Conference on Diabetes 1979

National Conference on Diabetes 1983

#### Juvenile Diabetes Foundation

Conference on Research Tissue 1981

National Meeting, Keynote Speaker 1984

International Scientific Research Conference 1985

#### German Diabetes Association, Giessen, West Germany

Islet Transplantation Workshop 1980

Islet Transplantation Workshop 1989

#### American Society of Artificial Organs

Annual Meeting - Keynote Speaker 1983

Session Co-Chairman 1987

#### International Symposium on Organ Transplantation in Diabetes

The Hague, Netherlands 1983

#### International Symposium on Kidney and Pancreas Transplantation

Perugia, Italy 1984

#### International Islet Transplantation Workshop

Canberra, Australia 1984

#### XII Congress of the International Diabetes Federation

Madrid, Spain 1985

#### XIII Congress of the International Diabetes Federation

Sydney, Australia 1989

#### National Disease Research Interchange

Human Tissue Conference 1985

Human Tissue Conference 1986

Human Tissue Conference 1987

Taman Tissue Conference 1707

Human Tissue Conference 1990

National Disease Research Interchange - Chairman of Task Force on "Biohazard and Contamination in the Use of Human Tissue and Organs"

Philadelphia, PA 1988

American Diabetes Association National Meeting - Session Co-Chairman for "Forms of Therapy" 1986

Visiting Scientist Program - University of Kansas Diabetes Center Kansas City, Kansas 1986

Immunology of Diabetes Symposium - Member of International Advisory Committee Edmonton, Canada 1986

International Symposium on Complications of Diabetes

The Hague, Netherlands 1986

Visiting Professorship - Department of Surgery - University of Minnesota Minneapolis, Minnesota 1986

May 8<sup>th</sup> Endocrine Days

Victoria, British Columbia 1987

Second Annual Visiting Professorship in Diabetes - University of Wisconsin Madison, Wisconsin 1987

First International Course on Transplantation

Venice, Italy 1987

Progress in Organ Transplants, Tissue Replacements and Implants Sponsored by Biomedical Business International, New York 1987

Josiah Brown Memorial Symposium on Pancreas Beta Cell Transplantation

Los Angeles, California 1987

Seventh Workshop of the AIDSPIT Study Group

Igls, Austria 1988

First international Congress on Pancreatic and Islet Transplantation

Stockholm, Sweden 1987

Thirty-Fourth Annual Meeting of ASAIO, Invited Speaker "Modern Treatment of Insulin Dependent Diabetes"

Reno, Nevada 1988

Sixth Gordon Research Conference on Drug Carriers in Biology and Medicine Plymouth, New Hampshire 1988

XII International Congress of the Transplantation Society

Sydney, Australia 1988

Second International Congress on Pancreatic and Islet Transplantation

Minneapolis, Minnesota 1989

Biology of Tissue Transplantation Symposium

Bethesda, Maryland 1989

Ninth Workshop of the AIDSPIT Study Group

Igls, Austria 1990

Society for Surgery of the Alimentary Tract Postgraduate Course, "Medical Aspects of Transplantation of the Liver, Pancreas and Intestine"

San Antonio, Texas 1990

Moderator for Pancreas Transplantation Scientific Session - American Society of Transplant Surgeons

Chicago 1990

UCLA Symposium on Molecular & Cellular Biology, "Tissue Engineering"

Keystone, Colorado 1990

The Huddinge Hospital Transplant Lectureship Annual Meeting of the Swedish Society for Medical Science

Stockholm, Sweden 1990

Third International Congress on Pancreatic and Islet Transplantation - Moderator and Plenary Speaker

Lyon, France 1991

European Association for the Study of Diabetes - Plenary Speaker Dublin, Ireland 1991

Visiting Professor - University of Wisconsin

Madison, Wisconsin 1991

Moderator for Clinical Transplantation-Pancreas and Islets - XVIth International Congress of the Transplantation Society

Paris 1992

American Diabetes Association 53<sup>rd</sup> Annual Meeting - Plenary Speaker Las Vegas, Nevada 1993

Fourth International Congress of Pancreas and Islet Transplantation - Plenary Speaker Amsterdam 1993

IVth Joint Meeting of the Lawson Wilkins Pediatric Endocrine Society and the European Society for Pediatric Endocrinology - Symposium Speaker

San Francisco 1993 American Association for Clinical Chemistry

New York 1993

#### **Publications**

#### Abstracts:

- 1. Ballinger, W.F., Lacy, P.E., Scharp, D.W. Kemp, C.B., Knight, M. Isografts and allografts of pancreatic islets in rats. Brit. J. Surg. 60:313, 1973
- 2. Kemp, C.B., Knight, M.J., Scharp, D.W., Lacy, P.E., Ballinger, W.F. Islets of Langerhans injected into the portal vein of the diabetic rat. South African Journal of Surgery 11:135, 1973
- 3. Kemp, C.B., Knight, M.J., Scharp, D.W., Lacy, P.E., Ballinger, W.F. Proceedings: Implantation of pancreatic islets into the portal vein of diabetic rats. Brit. J. Surg. 60:907, 1973
- 4. Scharp, D.W., Kemp, C.B., Knight, M.J., Murphy, J., Newton, W., Ballinger, W.F., Lacy, P.E. Long term results of portal vein islet isografts and allografts in the treatment of Streptozotocin induced diabetes. Diabetes 23:359, 1974
- 5. Scharp, D.W., White, D.J., Ballinger, W.F., Lacy, P.E. Transplantation of intact islets of Langerhans after tissue culture. In Vitro 9:364, 1974
- 6. Knight, M.J., Scharp, D.W., Kemp, C.B., Nunnelley, S.B., Ballinger, W.F., Lacy, P.E. Cryopreservation of pancreatic islets. European Surgical Research 6(1):89, 1974
- 7. Ballinger, W.F., Murphy, J.J., Scharp, D.W., Hirshberg, G.E., Karl, R.C., Lacy, P.E. Isolation and preservation of human islets of Langerhans for transplantation in the treatment of diabetes. European Society for Exp. Surg., Tenth Congress 1975
- 8. Griffith, R.C., Scharp, D.W., Ballinger, W.F., Lacy, P.E. A morphologic study of intrahepatic portal vein islet isografts. Diabetes 34(2):419, 1975
- 9. Dodi, G., Scharp, D., Feldman, S., Maresca, B., Ballinger, W., Lacy, P. Treatment of exocrine pancreatic dysfunction in diabetic rats by islet transplantation. European Surgical Research 9(1):98, 1977
- Scharp, D.W., Merrell, R.C., Feldman, S., Ruwe, E., Feldmeier, M., Ballinger, W., Lacy,
   P. Long term culture of islets of Langerhans utilizing a rotational culture method. In
   Vitro 13:174, 1977
- 11. Scharp, D., Krupin, T., Waltman, S., Oestrich, C., Feldman, S., Ballinger, W., Becker, B Relationship of abnormal insulin release to fluorophotometry in experimental diabetes. Diabetes 27(2):435, 1978

- 12. Scharp, D.W., Merrell, R.C., Feldmeier, M.M., Downing, R., Ballinger, W.F. Pseudo-islet formation and culture from canine isolated pancreatic cells. In Vitro 15:216, 1979
- 13. Rajotte, R.V., Scharp, D.W., Downing, R. Molnar, G.D., Ballinger, W.F. The transplantation of frozen-thawed rate islets transported between centers. Diabetes 28:377, 1979
- 14. Downing, R. Scharp, D.W., Grieder, M., Ballinger, W.F. Mass isolation of islets of Langerhans from the dog pancreas. Diabetes 28:426, 1979
- 15. Feldman, S.D., Scharp, D.W., Lacy, P.E., Ballinger, W.F. Fetal pancreas isografts, cultured and uncultured to reverse Streptozotocin induced diabetes mellitus. The Association for Academic Surgery 12:116, 1979
- 16. Grieder, M.H., DeSchryver-Kecskemeti, K. Gingerich, R.L., Scharp, D.W. In vitro studies using canine pseudo-islets and rat antrum cultures as models. UCLA Symposium, December 3, 1979
- 17. Scharp, D.W., Feldmeier, M.M., Rajotte, R.V., DeSchryver, K., Bell, M. Human pseudo-islet formation, culture and preservation. Diabetes 29(2):18A, 1980
- 18. Gingerich, R.L., Scharp, D.W., Grieder, M.H., Dye, E.S., Mousel, K.A. A new in vitro model to study secretion and biochemistry of pancreatic polypeptide (PP). Diabetes 29(2):30A, 1980
- 19. Bergen, J.F., Mason, N.S., Scharp, D.W., Sparks, R.E. Insulin inhibition of islets in transplantation chambers. Presented at International Society for Artificial Organs Meetings, Paris, July 8-10, 1981
- 20. Sparks, R.E., Mason, N.S., Finley, T.C., Scharp, D.W. Development, testing and modeling of an islet transplantation chamber, ASAIO Meetings, Chicago, April, 1982
- 21. Long, J.A., Adair, W.S., Scharp, D.W. Hybridoma production against pancreatic cells. Diabetes 31(2):20A, 1982
- 22. Scharp, D.W., Hirshberg, G., Long, J.A. The effect of islet dosage and time on rat portal vein isografts. Diabetes 31(2):162A, 1982
- 23. Scharp, D.W., Lacy, P.E. The isolation and alteration of islet tissue for transplantation. The Tissue Culture Association Meeting, San Diego, June, 1982. In Vitro Suppl. 1, 1982
- 24. Long, J.A., Adair, W.S., Scharp, D.W. An immunological approach to islet cell purification. J. Cell Biol. 95:4061, 1982

- 25. Sparks, R.E. Mason, N.S., Finley, T.C., Scharp, D.W. Design of islet transplantation chambers giving a normal glucose tolerance test. ISAO Meetings, Kyoto, Japan, November, 1983
- 26. Sparks, R.E., Mason, N.E., Finley, T.C., Scharp, D.W. Islet transplantation chamber models assumption for insulin generation and glucose diffusion. International Symposium on Organ Transplantation in Diabetes, The Netherlands, September, 1983
- 27. Sparks, R.E., Mason, N.S., Scharp, D.W. Some present directions in research on tissue transplantation chambers. International Conference on Artificial Organs, Glasgow, Scotland, September, 1983
- 28. Sparks, R.E., Mason, N.S., Finley, T.C., Scharp, D.W. "A distributed source-model for hybrid artificial pancreas", presented by ASAIO, Toronto, Ontario, Canada, April, 1983
- 29. Scharp, D.W., Feldmeier, M.M., Olack, B.J., Swanson, C.J., O'Shaughnessey, S.F. Electrophoretic purification of islet cells for transplantation. Diabetes 33(1):179A, 1984
- 30. Scharp, D.W., Rajotte, R.V., Kneteman, N.M., Lacy P.E. Zero gravity electrophoresis of islet cells. 10<sup>th</sup> International Congress of the Transplantation Society Meeting, Minneapolis, August, 1984
- 31. Scharp, D.W., Lacy, P.E. Human islet isolation and transplantation. Diabetes 34(1):5A, 1985
- 32. Kneteman, N.M., Alderson, D., Scharp, D.W. Canine pancreatic islet allotransplantation: dose adjusted cyclosporine A vs azathioprine steroid, Diabetes 34(1):62A, 1986
- 33. Alderson, D., Kneteman, N.M., Scharp, D.W. The isolation of purified human islets of Langerhans. Diabetes 34(1):81A, 1986
- 34. Corlett, M.P., Fonseca, P., Scharp, D.W. Detrimental effect of warm ischemia on islet isolation in rats and dogs with protection by oxygen free radical scavengers. Diabetes 36(1):223A, 1987
- 35. Scharp, D.W., Lacy, P.E., Finke, E.H., Olack, B.J. Seven day culture of Ficoll purified human islets. Diabetes 36(1):222A, 1987
- 36. Corlett, M.P., Scharp, D.W. Effect of warm ischemia on islet isolation in rats and dogs. The Association for Academic Surgery, Orlando, Florida, November 1-4, 1987
- 37. Misler, S., Gee, W., Scharp, D., Manchester, J., Falke, L. Metabolically regulated potassium channels in human islet cells. Diabetes 37(1):6A, 1988

- 38. Atkinson, M.A., Maclaren, N.K., Riley, W.J., Scharp, D.W., and Holmes, L. M<sub>r</sub> 64,000 autoantibodies (64KA) predict insulin dependent diabetes (IDD). Diabetes 37(1):98A, 1988
- 39. Scharp, D.W., Lacy P.E., Ricordi, C., Boyle, P., Santiago, J.V., Gingerich, R.L., Anderson, C.B., Flye, M.W. Human islet transplantation in patients with Type I diabetes. Presented at XII International Congress of the Transplantation Society, Sydney, Australia, August 14-19, 1988
- 40. Riley, W.J., Maclaren, N.K., Atkinson, M.A., Scharp, D.W., Lacy, P.E. Islet autoantibodies in "prediabetes". Ninth International Workshop on the Immunology of Diabetes, Satellite Symposium on Beta Cell Destruction and Restoration in Type I Diabetes. November 27-29, Sydney, Australia, 1988
- 41. Atkinson, M.A., Maclaren, N.K., Riley, W.J., Scharp, D.W., Holmes, L. The natural history and predictive value of M<sub>r</sub> 64,000 islet cell antigen. Ninth International Workshop on the Immunology of Diabetes, Satellite Symposium of the International Diabetes Federation, Melbourne, Australia, 1988
- 42. Scharp, D.W., Chern, H.T., McCullough, C.S., Gingerich, R.L. Lack of glucose induced insulin responsiveness in canine islets. 49<sup>th</sup> Annual Meeting of the American Diabetes Association, Detroit, Michigan, June 3-6, 1991. Diabetes 38(1):209A, 1989
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